



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,448	11/07/2001	David Lewis	Mirus.030.03	3784
25032	7590	03/09/2007		
MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719			EXAMINER GIBBS, TERRA C	
			ART UNIT	PAPER NUMBER
			1635	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/007,448

Applicant(s)

LEWIS ET AL.

Examiner

Terra C. Gibbs

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sept 9, '05, May 25, '06, and Dec 8, '06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9, and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Amendments and Remarks filed September 9, 2005, May 25, 2006, and December 8, 2006.

Claims 1, 3-9, and 13-16 are pending in the instant application.

Claims 1, 3-9, and 13-16 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

Applicant's Amendments and Remarks filed September 9, 2005, May 25, 2006, and December 8, 2006 are acknowledged.

Applicant's Petition under 37 CFR §1.78(a)(3) to accept a delayed claim benefit under 35 U.S.C 120 of filed copending nonprovisional application is acknowledged and has been granted.

Priority

It is noted that Applicants have been granted a petition under 37 CFR §1.78(a)(3) to accept a delayed claim benefit under 35 U.S.C 120. It is further noted that Applicants claim the benefit for this application under 35 U.S.C. 120 as a continuation in part of USSN 09/447,966, filed November 29, 1999, which claims benefit to provisional applications 60/121,730 and 60/146,564, filed February 26, 1999 and July 30, 1999, respectively, and is a continuation in part of nonprovisional application USSN

Art Unit: 1635

09/391,260, filed September 7, 1999, which is a divisional of nonprovisional application USSN 08/975,573, filed November 21, 1997, which is a continuation of USSN 08/571,536, filed December 13, 1995.

The Examiner would like to point out that the instant application claims priority to a laundry list of U.S. Provisional Applications and patented U.S. Patent Applications. First, the reference should be updated to reflect applications for patents that are abandoned. Particularly, see USSN 09/391,260, filed September 7, 1999. Second, due to the voluminous nature and number of the applications to which priority is claimed, Applicant are requested to point out with particularity where support for the instantly claimed invention may be found in one or more of the prior filed applications to which benefit is claimed, since such support is not readily apparent in the priority documents.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The Examiner fully acknowledges Applicant's claim for benefit, however, the instant claims have been afforded priority to November 7, 2001, which is the filing date of the instant application because support for the claims, drawn to a process for delivering a naked polynucleotide into a cell of a mammal to inhibit protein expression could not be found in any application which Applicants claim priority to.

Art Unit: 1635

Applicants claim the benefit for this application under 35 U.S.C. 120 as a continuation in part of USSN 09/447,966, filed November 29, 1999, now US Patent No. 6,627,616. While Patent 6,627,616 has support for a process for delivering a naked polynucleotide into a cell of a mammal, the Patent does not support a process for delivering a naked polynucleotide into a cell of a mammal **to inhibit protein expression**. The Examiner would like to note that Patent 6,627,616 discloses that a polynucleotide can be delivered to a cell to express an exogenous nucleotide sequence, to inhibit, an endogenous nucleotide sequence (see column 6, lines 36-39), however, this disclosure does not support inhibiting protein expression as instantly claimed.

Regarding provisional applications 60/121,730 and 60/146,564, while these Applications support a process for delivering a naked polynucleotide into a cell of a mammal, the **inhibition of protein expression** is not disclosed, neither implicitly nor explicitly.

Regarding USSNs 09/391,260, 08/975,573, and 08/571,536, none of these Applications disclose implicitly or explicitly, a process for delivering a naked polynucleotide into a cell of a mammal **to inhibit protein expression** as instantly claimed.

In summary, support for a process for delivering a naked polynucleotide into a cell of a mammal **to inhibit protein expression** is only found in the instant application, but not in any other application which Applicants claim priority to. Therefore, the instant application and claims have been afforded priority November 7, 2001, which is the filing date of the instant application.

Art Unit: 1635

If Applicants believe that they are entitled to an earlier priority date, the Examiner urges Applicant to specifically point where support can be found for a process for delivering a naked polynucleotide into a cell of a mammal **to inhibit protein expression** in any other applications Applicants claim priority to.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed July 27, 2005, claims 1, 3-6, 8 and 13-15 were rejected under 35 U.S.C. 102(b) as being anticipated by Kumasaka et al. (Journal of Clinical Investigation, 1996 Vol. 97:2362-2369). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed July 27, 2005.

In the previous Office Action mailed July 27, 2005, claims 1, 3-6, 8, and 13-16 were rejected under 35 U.S.C. 102(b) as being anticipated by Graham et al. (Journal of Pharmacology and Experimental Therapeutics, 1998 Vol. 286:447-458). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed July 27, 2005.

In the previous Office Action mailed July 27, 2005, claims 1, 3, 4, 5, 7, 9, and 13-15 were rejected under 35 U.S.C. 102(e) as being anticipated by Kay et al. [U.S. Patent No. 6,107,027]. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed July 27, 2005.

Response to Arguments

In response to these rejections, Applicants argue that since the Petition to claim the benefit of an earlier filing date was granted, the cited prior art is no longer prior art and should be removed as reference(s).

This argument has been fully considered, but is not found persuasive. While Applicant's Petition to claim the benefit of an earlier filing date has been granted, the instant claims have been afforded priority to November 7, 2001, which is the filing date of the instant application because support for the claims, drawn to a process for delivering a naked polynucleotide into a cell of a mammal to inhibit protein expression could not be found in any application which Applicants claim priority to. For more explanation and discussion, see the section above titled, "Priority".

In this regard, claims 1, 3-6, 8 and 13-15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kumasaka et al. Claims 1, 3-6, 8, and 13-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Graham et al. And claims 1, 3, 4, 5, 7, 9, and 13-15 remain under 35 U.S.C. 102(e) as being anticipated by Kay et al.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1635

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Art Unit: 1635

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

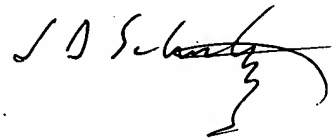
Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

tcg

March 2, 2007

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'J D Schultz', with a stylized flourish at the end.